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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,766	07/15/2003	Christopher Charles Abney	PR60153US1	8793

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EXAMINER	
STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,766	ABNEY ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,23,30-32,36-53,57 and 58* is/are pending in the application.

4a) Of the above claim(s) *19-22,24-29,33-35,54-56,59 and 60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,23,30-32,36-53,57 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/9/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicant's Election, *without traverse*, of Group I encompassing claims 1-18, 23, 30-32, 36-53 and 57-58, which was filed on October 25, 2005 in response to the Restriction Requirement as set forth in the Official Action mailed on October 7, 2005, is acknowledged.

Status of Claims

Claims 19-22, 24-29, 33-35, 54-56 and 59-60 are withdrawn from consideration as a result of the Applicant's Election, without traverse, of the claims of Group I for further prosecution. In regard to claims 23, 30-32 and 57-58 of the instant application, said claims are product-by-process claims that are dependent upon independent process claims, which are withdrawn from consideration as being directed to a non-elected invention. Therefore, claims 23, 30-32 and 57-58 of the instant application are examined only to the extent that said claims read upon a final pharmaceutical composition end product containing the specific ingredients set forth and explicitly recited within the withdrawn process claims. Pursuant to the aforementioned Election, claims 1-18, 23, 30-32, 36-53 and 57-58 are currently pending and therefore examined herein on the merits for patentability.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 36-39 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,365,196 (hereinafter the Venkatesh '196 patent).

With respect to claims 1-5 and 36-39 of the instant application, the Venkatesh '196 patent discloses a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition comprises: lithium carbonate; an optional pharmaceutically acceptable excipient; a dissolution rate stabilizer; a secondary release controlling agent; and a pigment (column 1, lines 9-22; column 2, lines 4-9, 40-46 and 56-63; column 3, lines 1-7 and 61-67; column 4, lines 1-40 and 59-67; column 5, lines 1-9 and 39-67; column 6, lines 1-6). Iron oxide pigment is present in trace amounts, such as 0.2% by weight of a 644 mg tablet or 1.29 mg, which is *about* 1 mg per tablet (column 1, line 21; column 4, lines 66-67; column 5, line 8). The optional pharmacological excipient further comprises a lubricant present in an amount of about 0.5% by weight to about 1.0% by weight, wherein said lubricant is magnesium stearate (column 1, line 21-22; column 4, line 61).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 8-10, 30-32, 40-46, 49-53 and 57-58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of U.S. Patent 5,425,950 (hereinafter the Dandiker '950 patent).

The teachings of the Venkatesh '196 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 8-10, 30-32, 40-46, 49-53 and 57-58 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition comprises: lithium carbonate; an optional pharmaceutically acceptable excipient; a cellulose derivative, such as microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose, as a disintegrant, filler and/or binder; and a secondary release controlling agent (column 1, lines 9-22; column 2, lines 4-9, 40-46 and 56-63; column 3, lines 1-7 and 61-67; column 4, lines 1-40 and 59-67; column 5, lines 1-9 and 39-67; column 6, lines 1-6). The pharmaceutical composition may further comprise iron oxide (column 1, line 21; column 4, lines 66-67; column 5, line 8). The lithium carbonate is present in an amount from about 40% by weight to about 90% by weight, preferably from about 65% by weight to about 85% by weight, and more preferably from aqbout 80% by weight to about 85% by weight (column 1, lines 18-19; column 2, lines 56-57; column 4, lines 27-29 and 66). The cellulose derivative, such as microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose, is present in an amount from about 5% by weight to about 30% by weight (column 2, lines 62-63; column 3, lines 4-6; column 4, lines 9-10 and 34-36). The optional pharmacological excipient further comprises a lubricant present in an amount of about 0.5% by weight to about 1.0% by weight, wherein said lubricant is magnesium stearate (column 1, line 21-22; column 4, line 61).

The Venkatesh '196 patent does not explicitly teach utilizing the sodium carboxymethylcellulose of claims 8-10, 30-32, 49-53 and 57-58. However, the Dandiker '950 patent teaches the interchangeability of sodium carboxymethylcellulose with microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose as a disintegrant, filler and/or binder (column 5, lines 59-62; column 6, lines 15-32). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose, as taught by the Venkatesh '196 patent, with sodium carboxymethylcellulose, as reasonably suggested by the Dandiker '950 patent. One of ordinary skill in the art would have been motivated to substitute sodium carboxymethylcellulose for the microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose disintegrant, filler and/or binder, as the utilization of sodium carboxymethylcellulose as a disintegrant, filler and/or binder is conventional in the art of formulating controlled release pharmaceutical compositions, as reasonably suggested by the Dandiker '950 patent.

In addition, the Venkatesh '196 patent does not explicitly teach utilizing the stearic acid of claims 32, 40-41 and 53; the calcium stearate of claims 32 and 45; nor the sodium stearyl fumarate of claims 32 and 42-44. However, the Dandiker '950 patent teaches the interchangeability of stearic acid, calcium stearate and sodium stearyl fumarate with magnesium stearate (column 5, lines 52-54, column 6, lines 1-2 and 31-32). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute magnesium stearate, as taught by the Venkatesh '196 patent, with stearic acid, calcium stearate and sodium stearyl fumarate, as reasonably suggested by the Dandiker '950 patent. One of ordinary skill in the art would have been motivated to substitute stearic acid, calcium stearate and sodium stearyl fumarate for the magnesium stearate lubricant, as the utilization

of stearic acid, calcium stearate and sodium stearyl fumarate as a lubricant are conventional in the art of formulating controlled release pharmaceutical compositions, as reasonably suggested by the Dandiker '950 patent.

2. Claims 11-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of U.S. Patent 4,346,709 (hereinafter the Schmitt '709 patent).

The teachings of the Venkatesh '196 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 11-16 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition comprises fumaric acid, as a secondary release controlling agent, which is present in an amount from about 1% by weight to about 15% by weight, preferably from about 3% by weight to about 15% by weight, and more preferably from about 6% by weight to about 13% by weight (column 2, lines 4-9, 45 and 67; column 3, lines 1-3; column 4, lines 23-24 and 37-39).

The Venkatesh '196 patent does not explicitly teach utilizing glycine as the secondary release controlling agent. However, the Schmitt '709 patent teaches the interchangeability, as well as the combination, of glycine with fumaric acid, as erosion rate controlling modifiers for controlling the rate of erosion and thus the rate of release of a drug (column 7, lines 30-40 and 54-56; column 8, lines 2-6 and 43-45). The Schmitt '709 patent also teaches utilizing an erosion rate controlling modifiers, such as glycine and/or fumaric acid, in an amount from about 0.001% to about 40% by weight (column 8, lines 2-6). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the

instant application was filed to substitute fumaric acid, as taught by the Venkatesh '196 patent, with glycine, as reasonably suggested by the Schmitt '709 patent. One of ordinary skill in the art would have been motivated to substitute glycine for fumaric acid, as the utilization of glycine is demonstrated to be a conventional erosion rate controlling modifier in the art, either alone or in combination with other erosion rate controlling modifiers, in the formulation of controlled release pharmaceutical compositions, as reasonably suggested by the Schmitt '709 patent.

3. Claims 17-18 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of the Dandiker '950 patent and in further view of the Schmitt '709 patent.

The teachings of the Venkatesh '196 patent, the Dandiker '950 patent and the Schmitt '709 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 17-18 and 23 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition comprises: lithium carbonate; an optional pharmaceutically acceptable excipient, such as a magnesium stearate lubricant; a cellulose derivative, such as microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose, as a disintegrant, filler and/or binder; and fumaric acid, as a secondary release controlling agent, which is present in an amount from about 1% by weight to about 15% by weight, preferably from about 3% by weight to about 15% by weight, and more preferably from about 6% by weight to about 13% by weight (column 1, lines 9-22; column 2, lines 4-9, 40-46, 56-63 and 67; column 3, lines 1-7 and 61-67; column 4, lines 1-40 and 59-67; column 5, lines 1-9 and 39-67; column 6, lines 1-6).

The Venkatesh '196 patent does not explicitly teach utilizing the sodium carboxymethylcellulose of claims 17-18 and 23. However, the Dandiker '950 patent teaches the interchangeability of sodium carboxymethylcellulose with microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose as a disintegrant, filler and/or binder (column 5, lines 59-62; column 6, lines 15-32). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose, as taught by the Venkatesh '196 patent, with sodium carboxymethylcellulose, as reasonably suggested by the Dandiker '950 patent. One of ordinary skill in the art would have been motivated to substitute sodium carboxymethylcellulose for the microcrystalline cellulose, hydroxypropylmethylcellulose and hydroxyproplycellulose disintegrant, filler and/or binder, as the utilization of sodium carboxymethylcellulose as a disintegrant, filler and/or binder is conventional in the art of formulating controlled release pharmaceutical compositions, as reasonably suggested by the Dandiker '950 patent.

In addition, the Venkatesh '196 patent does not explicitly teach utilizing the stearic acid, of claims 17 and 23; the calcium stearate, of claim 23; and the sodium stearyl fumarate, of claim 23. However, the Dandiker '950 patent teaches the interchangeability of stearic acid, calcium stearate and sodium stearyl fumarate with magnesium stearate (column 5, lines 52-54, column 6, lines 1-2 and 31-32). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute magnesium stearate, as taught by the Venkatesh '196 patent, with stearic acid, calcium stearate and sodium stearyl fumarate, as reasonably suggested by the Dandiker '950 patent. One of ordinary skill in the art would have been motivated to substitute stearic acid, calcium stearate and sodium stearyl fumarate for the magnesium stearate lubricant, as the utilization of stearic acid, calcium

stearate and sodium stearyl fumarate as a lubricant are conventional in the art of formulating controlled release pharmaceutical compositions, as reasonably suggested by the Dandiker '950 patent.

Furthermore, the Venkatesh '196 patent does not explicitly teach utilizing glycine, of claims 17 and 23, as the secondary release controlling agent. However, the Schmitt '709 patent teaches the interchangeability, as well as the combination, of glycine with fumaric acid, as erosion rate controlling modifiers for controlling the rate of erosion and thus the rate of release of a drug (column 7, lines 30-40 and 54-56; column 8, lines 2-6 and 43-45). The Schmitt '709 patent also teaches utilizing an erosion rate controlling modifiers, such as glycine and/or fumaric acid, in an amount from about 0.001% to about 40% by weight (column 8, lines 2-6). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to substitute fumaric acid, as taught by the Venkatesh '196 patent, with glycine, as reasonably suggested by the Schmitt '709 patent. One of ordinary skill in the art would have been motivated to substitute glycine for fumaric acid, as the utilization of glycine is demonstrated to be a conventional erosion rate controlling modifier in the art, either alone or in combination with other erosion rate controlling modifiers, in the formulation of controlled release pharmaceutical compositions, as reasonably suggested by the Schmitt '709 patent.

4. Claims 6-7 and 47-48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Venkatesh '196 patent in view of U.S. Pre-Grant Patent Application Publication 2002/0056206 (hereinafter the Pace '206 publication).

The teachings of the Venkatesh '196 patent are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 6-7 and 47-48 of the instant application, the Venkatesh '196 patent teaches a controlled release pharmaceutical composition in solid dosage form for oral administration in the treatment of manic depression, wherein said pharmaceutical composition is compressed into tablets (column 2, lines 10-12; column 3, lines 53 and 60).

The Venkatesh '196 patent does not explicitly teach a specific hardness and pressure utilized when compressing said pharmaceutical composition into tablets. However, the Pace '206 publication teaches compressing a pharmaceutical composition comprising a therapeutic agent, excipients and magnesium stearate into a solid tablet dosage form for oral administration, wherein said pharmaceutical composition is compressed at a hardness and pressure from about 2 kPa to about 9 kPa ([0285]). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to compress a pharmaceutical composition comprising a therapeutic agent, excipients and magnesium stearate into a solid tablet dosage form for oral administration, as taught by the Venkatesh '196 patent, at a hardness and pressure from about 2 kPa to about 9 kPa, as reasonably suggested by the Pace '206 publication. One of ordinary skill in the art would have been motivated to compress a pharmaceutical composition comprising a therapeutic agent, excipients and magnesium stearate at a hardness and pressure from about 2 kPa to about 9 kPa, so as to obtain a solid tablet dosage form for oral administration, as reasonably suggested by the Pace '206 publication.

Conclusion

Claims 1-18, 23, 30-32, 36-53 and 57-58 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and would have been reasonably suggested by the teachings of the cited prior art references. Furthermore, claims 19-22,

24-29, 33-35, 54-56 and 59-60 are withdrawn from consideration as being directed to a non-elected invention.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

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SUPERVISORY PATENT EXAMINER